PATENT
Case 807P028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 5,855,598)
Issued: January 5, 1999)
Leonard Pinchuk)
EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS)

REQUEST FOR ISSUANCE OF
A CERTIFICATE OF CORRECTION
PURSUANT TO RULE 323

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned attorney respectfully requests issuance of a Certificate of Correction to correct typographical errors of minor character. Accompanying the present request is a form PTO 1050 showing these requested changes.

The changes being requested are clearly ones which have occurred in good faith and correction thereof is believed to be in strict compliance with the purpose, scope and intent of Rule 323 of Practice in Patent Cases and 35 U.S.C. § 255.

A check payable to the order of the Commissioner of Patents and Trademarks in the amount of $100.00 covering the statutory fee for issuance of this requested certificate is enclosed. Favorable consideration and approval of this request is respectfully requested.

Respectfully submitted,

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Dated: June 25, 1999

PRINTER'S TRIM LINE

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,855,598

DATED : January 5, 1999

INVENTOR(S) : Leonard Pinchuk

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Cover Page, under "Attorney, Agent, or Firm", "Fitz-Gibbon" should read --FitzGibbon--.

Col. 4, line 56, "illustrated in of" should read --illustrated in--.

Col. 11, line 14, "means an" should read --means of an--.

Col. 13, line 45, "damages branched" should read --damages to branched--.

Col. 14, line 51, "liner, 122c" should read --liner 122c--.

Col. 16, line 40, "with invention" should read --with the invention--.

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PATENT NO. 5,855,598

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FORM PTO 1050 (Rev. 2-93)

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further elucidated in the following description with reference to the drawings, in which:

FIG. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction in accordance with the invention;

FIG. 2 is a cross-sectional view along the line 2—2 of FIG. 1;

FIG. 3 is a perspective view, partially cut away, of another embodiment of the expandable supportive endoluminal graft construction;

FIG. 4 is a cross-sectional view along the line 4—4 of FIG. 3;

FIG. 5 is a perspective view, partially cut away, of a further embodiment of the expandable luminal graft construction;

FIG. 6 is a cross-sectional view along the line 6—6 of FIG. 5;

FIG. 7 is a perspective view, partially cut away, of a bifurcated expandable supportive endoluminal graft construction;

FIG. 8 is a cross-sectional view along the line 8—8 of FIG. 7;

FIG. 9 is a somewhat schematic view illustrating an early step in the implantation of a device such as shown in FIG. 7;

FIGS. 10, 11 and 12 are generally schematic views along the lines of FIG. 9 showing expansion of the main body and the branches of this bifurcated device;

FIG. 13 shows this bifurcated supportive graft after completion of the expansion procedure;

FIG. 14 illustrates another embodiment of a bifurcated expandable supportive endoluminal graft construction;

FIGS. 15, 16 and 17 illustrate implantation and assembly of the graft of FIG. 14;

FIGS. 18, 19, 20 and 21 illustrate a component branched graft and various stages of its separate, component deployment within a body vessel to repair an aneurysm, FIGS. 18 and 19 showing deployment of a preferred branched, longitudinally indented trunk component, and FIGS. 20 and 21 showing separate deployment of two branch components within the trunk component;

FIG. 22 is a top plan view of an embodiment of a branching trunk component in accordance with the invention;

FIG. 23 is a cross-sectional view along the line 23—23 of FIG. 22;

FIG. 24 is a side elevational view of the branching trunk component as illustrated in FIGS. 22 and 23;

FIG. 25 is an end view of the structure as shown in FIG. 24;

FIG. 26 is a perspective, generally exploded view of an example of a fixture suitable for forming the longitudinal crease in this trunk component;

FIG. 27 is a longitudinal broken-away view of the fixture of FIG. 26 with a braided cylindrical tube positioned therein;

FIG. 28 is a view generally in accordance with FIG. 27, showing formation of opposing crease indents in the braided cylindrical tube during formation of this trunk component;

components are illustrated in FIG. 18 through FIG. 21, which also illustrate their separate deployment with respect to each other within an aortic trunk. Same is shown in connection with treating an aneurysm such as an abdominal aorto-iliac aneurysm. The device includes a trunk component 101 which, in the illustrated use, is designed to extend from below the renal arteries to a location between the proximal neck of the aneurysm and the aorto-iliac bifurcation. It will be understood that this trunk component could also be shorter so that it terminates just below the proximal neck of the aneurysm, for example of a length which terminates within the dent or crease 124. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means of an introducer containing compressed expandable supportive graft components.

More particularly, and with reference firstly to FIG. 18, a guidewire 102 is first inserted in accordance with known procedures so as to traverse the aneurysm 103. Next, an introducer, generally designed as 104 having the trunk component therewithin in a radially compressed state is inserted over the guidewire 102. The introducer is maneuvered such that it is properly positioned as desired, in this case at a location distal of the distal end of the aneurysm. Then, the sheath 105 of the introducer is withdrawn, such as by sliding it in a proximal direction while the remainder of the introducer 104 remains in place. As the sheath is withdrawn, the trunk 101 expands, eventually achieving the deployed or implanted position shown in FIG. 19. At this stage, the distal portion 106 of the trunk is well anchored into the blood vessel wall and is suitably deployed.

FIG. 20 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (FIG. 21) radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg 109 of the already deployed trunk component 101. This positioning is illustrated in FIG. 21. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery 110.

In a previous step, a guidewire had been passed through the appropriate vessel to iliac artery 112 until it crossed the aneurysm 103, while passing through the other leg 113 of the deployed trunk component 101. When the introducer for the previously radially compressed iliac component 115 had been removed, the component 115 had expanded radially and was deployed. Thus, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together as shown in FIG. 21, as well as generally depicted in FIGS. 29 and 30.

It will be noted that it is not required to actually attach the trunk component 101 and the tubular components 108, 115 together. In other words, these components are generally telescopically positioned with respect to each other. This telescopic feature allows some slippage between the trunk component and the tubular leg components, thereby providing a telescopic joint which functions as a slip bearing. It will be appreciated that it is generally desirable to firmly anchor portions of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs, flared ends and the like.

leg portions 109c and 113c are not so bonded to the stent portion 121c. This facilitates formation of the leg portions, which are typically pinched along the length of the legs in order to form at least one internal seam 126c. Leg openings 127c and 128c are thereby generally defined between this seam 126c and the adhesion zones 124c and 125c.

In FIG. 33, means are included in the trunk component 101d which provides enhanced securement upon implantation. A stent component 129d is included which has a substantially higher pitch angle (for example, between about 140° and 180°) than does the stent portion 121d therebelow within which the legs are positioned (for example, at a pitch angle of between about 70° and 90°). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121c of the trunk component 101c. A barb 130 is also shown in order to further assist in securement of the endoprosthesis to the artery wall. When desired, the barb-type of structure can be a backing ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

Any of the various expandable supportive endoluminal graft, or stent graft, constructions discussed or referred to herein can be used in order to construct devices in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable stents, self-expanding stents, and combinations of balloon expandable stents and self-expanding stents. Use can be made of ancillary equipment such as endoluminal stapling devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such as at a location which would be above the renal arteries. The objective is also to help to secure the device in place.

The prosthesis as discussed is deployed to replace or repair tubular bodies such as blood vessels, tracheas, ureters and the like, accommodating more than one conduit in order to divert flow to other branches of the tubular body. This allows for repair of a bifurcated area which is difficult to repair using a single-lumen device or a plurality of individual single-lumen devices. It is suitable for repair of damages to branched conduits or, conversely, to repair conduits which converge into a single branch.

A preferred use for the bifurcating endoluminal grafts discussed herein is for insertion into a branching blood vessel. Same is typically suitable for use in the coronary vasculature (the right, left common, left anterior descending, and circumflex coronary arteries and their branches) and the peripheral vasculature (branches of the carotid, aorta, femoral, popliteal arteries and the like). These bifurcated devices are also suitable for implantation into other branching vessels such as in the gastrointestinal system, the tracheobronchial tree, the biliary system, and the genitourinary system.

It will be appreciated that the expandable supportive grafts in accordance with the present invention will dilate and/or support blood vessel lesions and other defects or diseased areas, including at or in proximity to sites of vascular bifurcations, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the graft's interface with body components that

facilitate normal cellular invasion without stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially outwardly directed forces provided by expanding the endoprosthesis with a balloon catheter, using an ejection tube that allows a spring-into-place structure to be deployed from the end of a catheter into its expanded configuration, or by using a support component made of certain alloys exhibiting thermotransition characteristics by which they expand when heated, for example.

In addition to the support component structures illustrated herein, support structures include others having spring characteristics and those having a coil with circumferentially oriented fingers such as shown in Gianturco U.S. Pat. No. 4,800,882, incorporated by reference hereinto. U.S. Pat. Nos. 5,061,275, 5,219,355 and 5,336,500 relate to expanding or self-expanding endoluminal devices. Typically, these devices center on the use of a metallic structure imparting expansion attributes. U.S. Pat. Nos. 4,994,071 and 5,360,443 describe bifurcated devices which use expandable metallic stent structures and textile materials allowing branching of fluid flow. In general, materials of these patents, incorporated by reference hereinto, can be utilized in constructing components of the present invention.

More specifically, the tubular supportive component preferably is a braided tubular stent body made of metal alloy or any other material that is flexible, while being rigid and resilient when thus braided. Spring-type metals are typically preferred, such as stainless steel, titanium, stainless steel alloys, cobalt-chromium alloys, including alloys such as Elgiloy, Phynox and Conichrome. Thermal transition or memory function alloys such as nickel-titanium alloys including Nitinol are also suitable. Malleable metals including tantalum would be especially suitable for a structure that is not self-expanding.

Concerning the materials for the liner(s), they are typically polymeric materials in the form of a membrane or textile-like material, the objective being to reduce the porosity of the stent for proper tissue ingrowth and fluid tightness. Exemplary polymeric materials include polyesters such as polyethylene terephthalate, polyolefins such as polypropylene, or elastomeric materials such as polyurethane or silicone rubber. Combinations of these materials are also possible. In an especially preferred arrangement, the exterior liner which engages the tubular supportive component **121**, when provided, is made of a double tricot polyester mesh knit, typically a Dacron type of material, while the interior liner **122c** is made of a polyurethane. In an especially preferred arrangement, a thin coating or cover of polymer is provided over the braided wires of the tubular supportive component.

With further reference to the material out of which the cover and/or liner of the grafts in accordance with the present invention are made, the material must be stretchable with respect to the support component so that it will follow the movement of the endoprosthesis between its fully collapsed and expanded or implanted configurations. Polyurethanes are preferred. Particularly preferred is an especially crack-resistant, elastomeric and pliable polycarbonate urethane as described in Pinchuk U.S. Pat. Nos. 5,133,742 and 5,229,431, incorporated by reference hereinto.

In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more

identical as shown in FIG. 26. A larger sized mandrel cylinder will result in the formation of a larger trunk component leg **109**, **113**. This would typically also include shifting the location of the slits **135** so that the plane of blade insertion will line up with the troughs. It will be appreciated that the trifurcated arrangement is achieved by a three-component mandrel and three slits and blades that are 120° apart. Similarly, a four-branched structure would include four of each features, spaced 90° apart.

In a preferred arrangement for this embodiment, the thus deformed braided tubular supportive component is chemically and heat processed in order to set the desired diameter and mechanical properties of the main body. Once this flexible metallic stent with conformed shape is thus prepared, it is preferably lined as discussed elsewhere herein. It will be noted that the illustrated tubular braided mesh has a main cross-sectional area and has an outward flair at both ends. The braided structure is advantageously accommodated by the serrated structure of the blade edges **138**, **139** in that the wire elements of the braid are grasped and secured at the ends of the bifurcation.

The expandable supportive graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or disease being addressed, such as occlusion, stenosis, aneurysm, arteriovenosis fistula, trauma and the like, as well as upon the anatomy of the vessel. For example, it can be desirable to have the support component of the expandable supportive graft at locations other than throughout the entirety of the graft as specifically illustrated in FIGS. 1 through 4 hereof. The bifurcated graft of FIGS. 7 and 8 shows some separation along the support component, such as between the trunk 61 and the branches 62, 63. It is also possible, with the grafts in accordance with the present invention, to provide an expandable graft having its supportive property emanating from one or more support components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a support component which can be presented at one end, both ends, or spaced along the expandable supportive graft in accordance with the invention.

Such a structure is generally illustrated in FIG. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first support component 72 and another or second support component 73. The expandable supportive graft in accordance with the present invention provides the tailorability advantage of being able to vary within a single graft the configuration, structure and properties of the support component or components of the graft. These various properties allow the expandable supportive graft to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support may be particularly desirable at one location being treated, while a less rigid supportive area is needed at another, generally adjoining location. By the expandable supportive graft in accordance with this invention, a single graft can be deployed in order to effect two or more different functions. By achieving multiple support and/or repair functions with a single device, possible trauma to the patient is minimized by reducing the number of transluminal passages needed to address a situation that could otherwise require separate stents or grafts, each of which is separately deployed or implanted.

With further reference to the tailorability aspects, the present invention reduces the risk of compromising the patency of the passageways being treated. This is particularly true in treating lesions at or near vascular bifurcations, branches and/or anastomoses. Typical difficulties which can